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510(K) SUMMARY

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92.

APPLICANT	Nanosys, Inc. 2625 Hanover Street Palo Alto, CA. 94304 USA
CONTACT PERSON	Hugh Daniels, PhD Director of Life Sciences R&D Phone: (650) 331-2100, ext 2108 Fax: (650) 331-2101 e-mail: hdaniels@nanosysinc.com
TRADE NAME:	ATD – Advanced Trauma Dressing
COMMON NAME:	Trauma Dressing
CLASSIFICATION NAME:	Dressing, Wound
DEVICE CLASSIFICATION:	Unclassified
PRODUCT CODE	FRO
PREDICATE DEVICES:	Convatec Aquacel® Ag (K080383) Z-Medica QuikClot®eX (K072474)
DATE PREPARED:	April 30, 2010

Description of Device:

ATD is composed of an absorbent pad of carboxymethyl cellulose impregnated with ionic silver and then uniformly coated with silicon particles for the purpose of promoting rapid hemostasis. The hemostatic mechanism of silicon in ATD is through, contact pathway activation (intrinsic) of clot formation.

The device is provided as a sterile 10 cm x 100 cm strip that is Z-folded and vacuum packed. The dressing is placed directly on the site of bleeding with applied pressure as long as necessary or until the time of definitive care.

Indications for Use:

Prescription Use:

ATD is intended for temporary external use to control traumatic bleeding.

Over-The-Counter-Use:

ATD is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Description of Substantial Equivalence:

ATD has the same intended use and technological characteristics as the predicate devices QuikClot®eX (K072474) and Aquacel® Ag (K080383) and therefore is substantially equivalent to the predicates.

ATD consists of the same absorbent material (carboxymethyl cellulose) and contains the same concentration of silver ions as Aquacel® Ag. ATD is coated with an equivalent hemostatic agent (silicon vs silicate based particles) that are in the same size regime as QuikClot®eX. This results in ATD having an identical mechanism of action, namely contact pathway activation (intrinsic) of clot formation as the predicate.

Performance Data:

Bench and animal testing has demonstrated equivalency of performance between ATD and the predicate devices. Performance testing included a comparison of material properties in bench testing and hemostatic performance in three in vivo porcine models of acute bleeding. ATD was shown to have equivalent hemostatic properties to QuikClot-eX in bench top coagulation studies and in 3 separate injuries performed on swine. In addition, ATD has demonstrated biocompatibility through the same four biocompatibility tests that the predicate device (QuikClot-eX) was subjected to and is provided sterile by gamma sterilization which is the same as the predicate.

Conclusion:

In summary, ATD and the predicate devices have the same intended use, design, material, and performance characteristics and no new questions of safety or effectiveness have been raised. Nanosys Inc. considers ATD to be substantially equivalent to the legally marketed predicate devices QuikClot®eX (K072474) and Aquacel® Ag (K080383), for the purpose of this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 1 2011

Nanosys, Inc.
% Hugh Daniels, Ph.D.
2625 Hanover Street
Palo Alto, California 94304

Re: K101257
Trade/Device Name: Advanced Trauma Dressing (ATD)
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 14, 2011
Received: November 15, 2011

Dear Dr. Daniels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101257

Device Name: Advanced Trauma Dressing (ATD)

INDICATIONS FOR USE:

Prescription use:

ATD is intended for temporary external use to control traumatic bleeding.

Over-The-Counter-Use:

ATD is intended for temporary external use to stop bleeding of superficial wounds, minor cuts, and abrasions.

Prescription Use x (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101257